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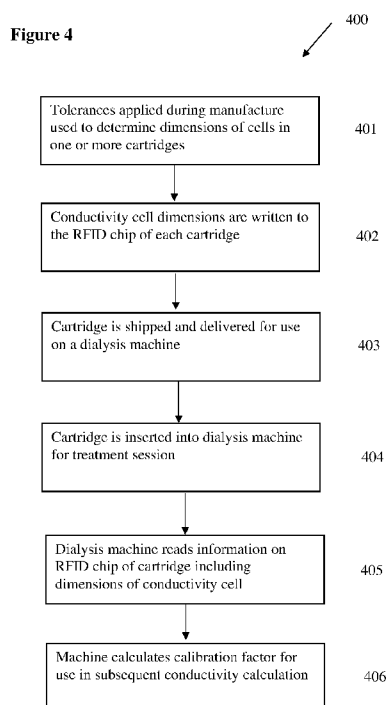
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(54) Title: DIALYSIS CASSETTE WITH RFID CHIP

Figure 4



(57) Abstract: A fluidic cartridge for use with a dialysis system, a method of manufacturing the fluidic cartridge, a dialysis machine and a method of operating the dialysis machine with the fluidic cartridge. The fluidic cartridge has a data storage unit, the data storage unit stores data relating to one or more physical properties of the cartridge. A cartridge for use in a portable dialysis machine and a portable dialysis machine. The cartridge has a data storage unit, the data storage unit stores data relating to sterilisation of the cartridge.



**DIALYSIS CASSETTE WITH RFID CHIP**Field of the invention

- 5 [0001] The present invention relates to the storage of data on a component of a medical device and exchange of data between the component and the medical device. More particularly, the invention relates to the exchange of data stored on a cartridge for use in a dialysis machine.

10 Background of the invention

- [0002] Haemodialysis is a blood filtration treatment performed on a patient with impaired renal function. A dialysis machine is connected to a patient's blood flow and the removes harmful waste substances from the blood before the blood is pumped back  
15 into the patient. Operation of the dialysis machine utilises a cartridge, whose function is to prepare dialysate (cleaning) solution and to balance flow of the dialysate. To do this, the cartridge comprises a complex arrangement of valves, membranes and fluid cavities. It is known in the art to provide disposable, single-use cartridges which eliminate the inherent hygiene issues associated with cleaning non-disposable  
20 cartridges.

- [0003] It will be appreciated that, for proper dialysis machine operation and function, and, by extension, improved patient experience, it is imperative that the cartridge complies with various manufacturing, storage, and usage standards and requirements  
25 and that certain parameters of the cartridge fall within permissible limits, values and/or variations. Current dialysis systems do not allow for the capture or analysis of characteristics which facilitate the determination of whether such standards and tolerances are met. Moreover, current dialysis systems have inherent limitations which mean that they are unable to efficiently accommodate variations in parameters of the  
30 cartridge, where such variations are a result of the manufacturing process.

[0004] It is an aim of the present invention to mitigate at least some of the above-mentioned drawbacks.

Summary of the invention

5 [0005] Accordingly, a first aspect of the invention provides a fluidic cartridge for use with a dialysis machine, the cartridge comprising a data storage unit for storing data in a readable, writable and non-volatile manner, wherein the data storage unit stores data relating to one or more physical properties of the cartridge which are a result of the tolerances applied during manufacture of the cartridge.

10 [0006] The fluidic cartridge facilitates the storage of information relating to the cartridge which can be read by a dialysis machine and/or a separate data reader. By allowing the dialysis machine to adjust its operation based on data received from the cartridge, variations in cartridge parameters can be compensated for by the machine, and manufacturing tolerances for the cartridge can be relaxed accordingly, which in turn  
15 means that the cost of manufacturing the cartridges can be reduced.

[0007] The data storage unit may be an RFID chip.

20 [0008] The data storage unit may be readable and preferably writable by a dialysis machine.

[0009] The data may include information relating to any one or more of the age of the cartridge, the intended function of the cartridge, the intended operation of the cartridge, the person or persons for whom the cartridge is to be used, the extent of usage of the  
25 cartridge, the intended geographical usage of the cartridge, the software intended for or required for use with the cartridge, the origin of the cartridge, sterilisation of the cartridge and storage and transportation of the cartridge.

[0010] According to a second aspect of the invention, there is provided a method of  
30 manufacture of a fluidic cartridge for use with a dialysis machine, the method comprising providing a cartridge, securing a data storage unit on to the cartridge and writing, to the data storage unit, information relating to one or more physical properties

of the cartridge which are a result of tolerances applied during manufacture of the cartridge.

5 [0011] The fluidic cartridge according to the first aspect of the invention may be manufactured according to the second aspect of the invention.

[0012] According to a third aspect of the invention, there is provided a dialysis machine comprising an interface for receiving a fluidic cartridge according to the first aspect of the invention, data reading means for reading data stored on a data storage unit on a  
10 fluidic cartridge, and a processor for receiving data stored on the data storage unit of the fluidic cartridge, wherein the processor comprises executable instructions, wherein the executable instructions comprise instructions for adjusting an operational parameter of the dialysis machine based on the received data.

15 [0013] The dialysis machine is able to extract data from a cartridge and send the data to a central storage facility for analysis. The quality, use and authenticity, at least, of the cartridge can be monitored in this way.

[0014] An operational parameter may comprise a conductivity cell calibration factor.  
20

[0015] The executable instructions may further comprise instructions for calculating the conductivity of dialysate solution in a conductivity cell of the cartridge based on the conductivity cell calibration factor.

25 [0016] The dialysis machine may further comprise transmitting means for transmitting data read by the data reading means to a remote storage facility.

[0017] According to a fourth aspect of the invention, there is provided a method of operating a dialysis machine, comprising the steps: providing a dialysis machine  
30 comprising means for reading data stored on a data storage facility of a dialysis cartridge, providing a dialysis cartridge for use with the dialysis machine, wherein the cartridge comprises a data storage facility storing data relating to physical parameters of the cartridge which are a result of tolerances applied during manufacture of the

cartridge, reading, by the dialysis machine, information stored on the cartridge, calculating, by the dialysis machine, a calibration factor based on the information read from the data storage facility of the cartridge.

- 5 [0018] The method may further comprise calculating, by the dialysis machine, the conductivity of dialysate in a conductivity cell of the cartridge based on the calculated calibration factor.

[0019] According to a fifth aspect of the invention, there is provided a cartridge for use  
10 in a portable dialysis machine, wherein the cartridge comprises data storage means for storing data, wherein the data storage means stores data relating to sterilisation of the cartridge, and wherein the data storage means is configured such that when the cartridge is connected to the dialysis machine, data stored on the data storage means is read by the dialysis machine.

15

[0020] The stored data may comprise information relating to whether the cartridge has been sterilised since it was last used.

[0021] The data storage means may be at least one of an optical pattern, physical  
20 pattern, RFID chip or RFID tag.

[0022] The data storage means may be configured to be written to by the dialysis machine.

25 [0023] The data on the data storage means data may be read and written to by a device other than a dialysis machine.

[0024] The data stored on the data storage means may further include information relating to any one or more of the age of the cartridge, the intended function of the  
30 cartridge, the intended operation of the cartridge, the person or persons for whom the cartridge is to be used, the extent of usage of the cartridge, the intended geographical usage of the cartridge, the software intended for or required for use with the cartridge,

the origin of the cartridge, sterilisation of the cartridge and storage and transportation of the cartridge.

[0025] According to a sixth aspect of the invention, there is provided a portable dialysis machine, the machine comprising data reading means for reading data stored on data storage means of a cartridge when the cartridge is loaded in the machine, a processor, wherein the processor is configured to receive the data from the data reading means and to determine, from the stored data, whether the cartridge is suitable for use with the machine, wherein the processor is further configured to output information to be displayed on a user interface of the machine, wherein the output information relates to the determination as to whether the cartridge is suitable for use by the machine.

[0026] The machine may further comprise data writing means for writing data to a data storage means of a cartridge when the cartridge is loaded in the machine.

[0027] The data writing means may be configured to write data relating to the usage of the cartridge after the cartridge has been used.

[0028] The dialysis machine may further comprise transmitting means for transmitting data read by the data reading means to a remote storage facility.

[0029] International Patent Publication No. WO2015/022537 describes a blood treatment device capable of delivering haemodialysis and/or haemodiafiltration treatments to a patient. The device includes a cartridge on which dialysate for use in either treatment is mixed. A detailed description of the operation of the machine is set out at paragraphs [0068] to [0140] with reference to the accompanying figures. The contents of that description are hereby incorporated by reference thereto. The description of the device in WO2015/022537 sets out that a cartridge of the type described herein is received in the device to effect mixing of dialysate ingredients into mixed dialysate and to supply the mixed dialysate to a dialyser cartridge in accordance with a specific treatment mode.

[0030] WO2015/022537 describes that the control system 500 activates the valves and pumps on the device/cartridge to effect different treatment modes, particularly haemodialysis (described at paragraphs [0120] to [0123]) and different haemodiafiltration modes (described at paragraphs [0124] to [0139]).

5

[0031] Presently, the control system 500 on the device requires intervention by a medical practitioner to operate a particular treatment protocol. For example, the device allows a user manually to initiate one of the treatment modes. It also allows the user to program the device to operate the machine in a first treatment mode for a first period and a second treatment mode for a second period.

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[0032] According to a seventh aspect of the invention, there is provided a fluidic cartridge for use in a dialysis machine, wherein the cartridge comprises a data storage unit for storing data, wherein the data storage unit stores data relating to a patient treatment protocol.

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[0033] In that way a specific patient treatment protocol can be loaded onto the cartridge and when the cartridge is installed in the device, the control system 500 reads the treatment protocol and operates the device accordingly, removing the need to program the device with the treatment protocol.

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[0034] The patient treatment protocol data may include one or more of length of treatment, treatment modes to be performed by the machine, the length of time such modes are performed, the number of times such modes are performed and the frequency thereof.

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[0035] According to an eighth aspect of the invention, there is provided a dialysis machine comprising data reading means for reading data stored on the data storage unit of the fluidic cartridge of the seventh aspect when the cartridge is loaded in the machine, and a processor, wherein the processor is configured to receive the patient treatment protocol data read from the data storage unit by the data reading means and to operate the machine to deliver the patient treatment protocol.

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Brief description of the figures

5 [0036] Embodiments of the present invention will now be described, by way of example only, and with references to the accompanying drawings, in which:

[0037] **Figure 1** is a perspective view of a portable haemodialysis machine;

10 [0038] **Figure 2** is a perspective view of a portable haemodialysis machine;

[0039] **Figure 3** is a perspective view of a disposable cartridge according to an embodiment of the present invention;

15 [0040] **Figure 4** is a flow diagram of a method of data storage and transfer according to an embodiment of the invention.

Detailed description

20 [0041] A dialysis system generally comprises a dialyser which receives blood which is pumped by a peristaltic pump from a patient via an arterial line. The dialyser comprises a semi permeable membrane which separates the blood from dialysate solution, which removes impurities from the blood. Cleaned blood is returned to the patient via a venous line. Clean dialysate solution is pumped into the dialyser and spent, unclean dialysate solution is removed from the dialyser. A known portable dialysis system utilises a  
25 cartridge to mix clean dialysate solution and deliver it, at an appropriate flow rate, to the dialyser.

[0042] According to an embodiment of the invention, the function of the dialysis system described above is performed by a portable dialysis machine 100 as shown generally in  
30 Figure 1. This machine is substantially the same as that described in WO2015/022537 with the additional features described below. Connections to a patient are not shown for clarity. User interface 102 on the front panel of machine 100 allows a patient and/or caregiver to interact with machine 100 and input information (such as treatment session

parameters, instructions relating to cleaning and maintenance etc.) and to view information output by machine 100 (such as diagnostics, help and troubleshooting instructions, treatment session data, etc.).

5 [0043] Figure 2 shows dialysis machine 200 without the front panel and Figure 3 shows a disposable cartridge 300 which is configured to fit within machine 200 adjacent to interface 203 of machine 200. Cartridge 300 is typically made from medical grade acrylic plastic and has a machine side and a patient side. Machine side is configured to lie adjacent to interface 203 of machine 200. Cartridge 300 comprises a complex  
10 arrangement of pump chambers, valves and fluid passageways. The pump chambers are sealed by diaphragms which are typically formed from DEHP-free PVC and preferably all diaphragms are provided by a continuous sheet of material on machine side of cartridge 300. Individual diaphragms are operable by the application pneumatic pressure supplied by corresponding valves of interface 203 of machine 100, as described  
15 further in applicant's prior publication WO2015022537.

[0044] In one embodiment, a passive RFID chip or tag 304 is securely fixed to cartridge 300 during manufacture. Various data is written to chip 304 before cartridge 300 is sealed in packaging. The data is written to chip 304 using techniques that are known in  
20 the art. In other embodiments, data is stored on cartridge 300 by other means known in the art, such as by optical pattern, e.g. barcode or QR code. Alternatively (or additionally) a physical barcode is integrated on an area of the cartridge by injection moulding. A moveable dongle or tab may also be adopted, as well as pins whose electrical connections convey various information. In one embodiment, machine 100  
25 comprises a RFID reader which reads information stored on passive RFID chip 201 of cartridge 200. Dialysis machine 100 also comprises an RFID writing facility to write additional data to RFID chip 201.

[0045] The use of an authentic, certified, and appropriate cartridge is important for  
30 correct machine operation and improved patient experience. Accordingly, the storage of relevant data on a cartridge in accordance with the present invention allows a dialysis machine to verify, when the cartridge is inserted into the machine and before commencement of a treatment session, that the inserted cartridge has been

manufactured by a trusted and authorised manufacturer, that it is of a type suitable for the intended operation of the machine (for example, treatment or cleaning) and that its condition has not been compromised by incorrect storage, amongst other things.

5 [0046] To avoid the use of counterfeit cartridges and ensure only authentic cartridges can be used by the dialysis machine, a unique locking code is written to each authentic cartridge. Every unique locking code is known by every dialysis machine and so when a cartridge is inserted into a dialysis machine, the machine is able to match (or otherwise) the cartridge's locking code with one stored on the machine. If the locking  
10 code stored on chip 304 and read by machine 200 cartridge is not recognised by the machine (or indeed if the cartridge does not store a unique locking code), operation of the machine with the cartridge is denied. In an alternative embodiment, use of a cartridge is denied if it does not comprise any data storage unit or facility which is readable by the dialysis machine.

15

[0047] Dialysis cartridges may be of different types, where each type is suitable for a different purpose. For example, treatment cartridges are suitable for use during dialysis treatment (and are generally referred to herein simply as a 'cartridge'). Cleaning cartridges are suitable for use during a cleaning operation of a dialysis machine. A  
20 cleaning cartridge allows the machine to be subjected to a hot water or a sterilizing solution (citric acid) throughflow for cleaning. Indicator holes are made in the cleaning cartridge depending on the type of cleaning enabled by the cartridge. These holes are sensed by the machine by means of two retractable sensor pins which pass through a hole or, in the absence of a hole, are depressed by the cleaning cartridge body. The  
25 absence of any holes corresponding to the sensor pins is indicative of a proper dialysis cartridge.

[0048] Furthermore, particular cartridges are intended for use in specific models and makes of dialysis machines and are manufactured accordingly. Use of cartridges which  
30 are not intended for use on particular machines (and therefore may not have undergone strict testing and adherence to certain regulations) may therefore cause damage to the dialysis machine, impaired operation and ultimately compromise patient experience. To address this, data verifying the authenticity of a cartridge can be written to chip 201

during or after manufacture so that machine 100 can determine that the inserted cartridge 200 is suitable for use with the type, model and specification of machine 100 and that the cartridge has been manufactured at an authorised source and/or according to other predetermined criteria.

5

[0049] It is possible to reuse dialysate solution by cleaning it using sorbent. Dialysate which has been cleaned in this way does not require the addition of as many electrolytes to be usable again. As such, some parts of a cartridge (which mixes the dialysate during treatment) are redundant if cleaned dialysate is used. The suitability of a cartridge for such operation can be stored on the cartridge's chip.

10

[0050] In accordance with the above, information which is written to chip 304 before, during or after manufacture includes the cartridge's age/date of manufacture, batch number, intended function (i.e. travel mode, hemodiafiltration (HDF), for use with recycled dialysate), intended operation (i.e. whether it is intended for a specific type of operation, e.g. valve sequencing), whether it is intended for a particular patient or class of patients, its maximum usage duration (for example, maximum number of hours it can be used for, which may be based on the particular method of sterilisation of the cartridge), whether it has been sterilised and by what method it has been sterilised (e.g. gamma sterilisation, ethylene oxide, e-beam), whether it is intended for use in a particular geographical area (e.g. UK or US, where different countries or geographical areas stipulate different manufacturing standards, etc.), the cartridge's usage expiry date, and whether a dialysis in which the cartridge is used requires a software update for proper functioning with the particular cartridge.

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[0051] It is known to record information relating to storage conditions, origin, specification, etc. on labels on the packaging of cartridges. When the cartridge is first used, however, the packaging is usually discarded and therefore the information on the label cannot be read usefully at a later date. Advantageously, the use of RFID chips on the cartridge to store data means that data is readable throughout the life of the cartridge and data can be written to the cartridge during its life. During transportation to its intended final destination, a cartridge may pass through a number of countries, ports, warehouses, and modes of transportation. At various stages during transportation, data

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is written to RFID chips of cartridges, by RFID writers located, for example, in storage locations or in transportation, specifying the date and time the cartridge entered and left the storage location or transport, any particular treatment it was subjected to (e.g. additional sterilisation) and the conditions it has been stored or transported under (e.g. temperature, humidity, UV level, pressure). Prolonged exposure to daylight may, for example, increase the risk of perishing of parts of the cartridge (even if sealed) and consequently knowledge of the duration of daylight exposure allows the machine 100 (or indeed another RFID reader) to determine whether the cartridge is fit for use. Associated risks may also apply to storage at temperatures outside of a predefined temperature range (which may cause rupturing of membranes), to storage at pressures outside of a predefined pressure range and to storage outside of a predefined humidity range.

[0052] Most cartridges are 'disposable', i.e. they are manufactured as safe to use for a single dialysis session (i.e. they have a maximum usage duration). However, under certain conditions, they can be re-used provided the maximum usage duration has not been exceeded. For example, a particular patient may use a particular cartridge for a dialysis session lasting 2 hours. The maximum usage duration of the cartridge is 4 hours. It is possible for the same cartridge to be re-used by the same patient for the remaining two hours, in the same or a different dialysis machine. Once the initial 2 hour dialysis session is complete (but before cartridge 300 is removed from dialysis machine 100), dialysis machine 100 writes to chip 304 of cartridge 300 the number of hours and minutes of usage, i.e. the amount of time for which the cartridge has been used. When the cartridge is inserted into a different dialysis machine (or when machine 100 is instructed to start a new dialysis session using the same cartridge 300) the dialysis machine is able to read, from chip 304, the maximum usage duration of cartridge 300 and the current duration of usage (in this case, two hours). In this way the machine is able to determine how long the cartridge can be used for before its maximum usage duration is reached and therefore whether or not the cartridge can be used for the intended dialysis session.

[0053] In addition, machine 100, after completion of the initial dialysis session, writes data to the cartridge to identify the particular person it has been used for. This data may

take the form of a unique number, and allows the same or a different dialysis machine to verify, based on the separate entry of the unique number, that the cartridge 'matches' the patient who intends to use it for a subsequent dialysis session.

5 [0054] In some instances, it is desirable for cartridges to be re-used (within their maximum usage duration) for a person other than the person who first used the cartridge. As will be appreciated, for a cartridge to be reused in this way safely, the cartridge requires sterilisation. In this case, data confirming (or otherwise) that the cartridge has undergone sterilisation is written to chip 201 once disinfection and  
10 sterilisation is complete and such data is read by a dialysis machine (where appropriate, in conjunction with data relating to the previous user) such that the machine can determine whether or not the cartridge has been appropriately sterilised and is suitable for re-use.

15 [0055] Some or all of the information stored on all or a sample of cartridges during a specified time period is transmitted from a dialysis machine to a central server to facilitate monitoring of and data collection relating to cartridge usage. In one embodiment, each dialysis machine is configured to periodically send data relating to cartridge use and conditions to a central server via wired or wireless internet connection.

20

[0056] A main function of a cartridge (such as a cartridge discussed above) is to prepare dialysate and balance flow of the dialysate. Dialysate is a sterilized solution of mineral ions in an acid buffer and a bicarbonate buffer mixed with sterilized water. The required composition of the dialysate differs between patients and it is of critical importance that  
25 the composition for a particular patient is accurate to within clinical tolerances. It is the job of the dialysis machine, programmed correctly, to instruct the mixing of the dialysate within the cartridge according to the requirements of a particular patient.

[0057] The composition of dialysate can be determined to a high degree of accuracy by  
30 measuring the conductivity of the dialysate solution. Conductivity is determined by measuring the electrical current, and is variable dependent on the concentration of ions of sodium chloride in the dialysate solution. A cavity, or cell, of the cartridge receives mixed dialysate before it is passed on to the dialyser. Conductivity of the dialysate in

the cell is typically determined using sensing pins, as is known in the art. To accurately measure conductivity, the cross sectional area of the cell and the distance between the pins must be known.

5 [0058] In a further embodiment, the RFID chip 304 is programmed with data relating to a patient treatment protocol. When installed into the machine 200, the RFID reader reads the patient treatment protocol data and passes that data to a control processor on the machine 200. The control processor then operates the machine 200 to deliver the patient treatment protocol. The patient treatment protocol data may be the length of  
10 time that the machine delivers dialysis treatment. It may relate to delivery of one or more specific treatment modes including the length of time each mode is delivered and the order in which each mode is delivered. The data may be an executable instruction which the processor executes to control the machine.

15 [0059] Currently, both cartridge (including the volumes of the dialysate cells) and machine components are manufactured to very high specifications. For example, in order for an exact amount of dialysate to be pumped during a dialysis session of a specified duration, the size of each cavity of a cartridge is specified to a high degree of accuracy to ensure that operation of the dialysis machine, and ultimately, patient  
20 experience, is achieved. Tolerances are the permissible limits or the permissible variation in limits that are applied to parameters of the cartridge when it is manufactured. As an example, it may be specified that a fluid cell or cavity of the cartridge has nominal (i.e. and intended and precise) values for dimensions (e.g. height and width). The manufacturing process, however, means that, in reality, the dimensions  
25 of the cell/cavity have an error value (i.e. tolerance) either above or below (or both above and below) the nominal values. In order to ensure treatment or operational parameters which rely on the dimensions of the cell/cavity are calculated to a high degree of accuracy, the tolerances resulting from the manufacturing process are currently made as high as possible (i.e. the error values are as small as possible).

30

[0060] However, cartridges 200 are manufactured in massively larger quantities than the dialysis machines 100 themselves due to the disposable nature of the cartridges. Manufacturing such a large quantity of cartridge 200 to within such high tolerances can

slow down manufacture lead times and drive up manufacturing costs. Any variation between what is expected, by the machine, as the cell cross-section (based on specified nominal values of width and height), and the actual cell cross section (which differs from the nominal value as a result of random errors inherent in the manufacturing process) is typically input manually to the machine by a user of the machine. The packaging of each cartridge may comprise printed information detailing the actual measured parameters and dimensions of various cartridge parts and components and this information is manually input when the cartridge is loaded into the dialysis machine. The dialysis machine then makes the necessary calibration calculations accordingly. Manual input, however, is inherently error-prone and time consuming.

[0061] Advantageously, it has been realised by the inventors of present invention that drawbacks relating to the need for high tolerances for manufacture of cartridges and risk of false entry of critical cartridge parameters can be mitigated by storing actual dimensions (which deviate from the nominal values as a result of manufacturing tolerances) for a particular cartridge or batch of cartridges onto a data storage facility located on the cartridge itself, such as a passive RFID chip as discussed above. When the cartridge is loaded into a machine but before dialysis is begun, the machine reads the actual dimension and parameter data for the particular cartridge. The machine is then able to adjust one or more operational parameters accordingly (for example, by increasing the duration of the dialysis session if the machine determines that one of the cavities of cartridge has a volume which is  $1\text{mm}^3$  smaller than expected than the specified nominal value). By allowing for the machine to compensate for deviations in cartridge parameters as a result of manufacturing tolerances, rather than applying very high tolerances during manufacture, the cartridge can be manufactured more quickly and cheaply.

[0062] Figure 4 provides an overview of a process 400 of adjusting treatment parameters based on critical conductivity cell parameters of the cartridge. At step 401, the tolerances that are applied during manufacture are used to determine the dimensions of conductivity cells of one or more cartridges. These dimensions are written to an RFID chip located on each cartridge at step 402, by means known in the art. Each cartridge is sealed in packaging before being shipped and eventually delivered at its final

destination at step 403. At steps 404 and 405, a cartridge is inserted into a dialysis machine and an RFID reader of the dialysis machine reads the conductivity cell dimensions, along with any other information (as discussed above) on the cartridge's RFID chip. In an alternative embodiment, the RFID chip stores one or more tolerances (for example, a pair of tolerances (upper and lower) for one or more physical dimensions of the cartridge, such as conductivity cell dimensions, and the dialysis machine determines the dimensions of the conductivity cell to be used in a subsequent calibration calculation). At step 406, a processor of the dialysis machine calculated a calibration factor which will be required for subsequent determination of the conductivity of the dialysate solution.

Claims

1. A fluidic cartridge for use with a dialysis system, the cartridge comprising  
a data storage unit for storing data in a readable, writable and non-volatile  
5 manner, wherein the data storage unit stores data relating to one or more physical  
properties of the cartridge which are a result of the tolerances applied during  
manufacture of the cartridge.
2. The cartridge of claim 1, wherein the data storage unit is an RFID chip.
- 10 3. The cartridge of claim 1 or claim 2, wherein the data storage unit is readable and  
preferably writable by a dialysis system.
4. The cartridge of any preceding claim, wherein the data includes information  
15 relating to any one or more of the age of the cartridge, the intended function of the  
cartridge, the intended operation of the cartridge, the person or persons for whom the  
cartridge is to be used, the extent of usage of the cartridge, the intended geographical  
usage of the cartridge, the software intended for or required for use with the cartridge,  
the origin of the cartridge, sterilisation of the cartridge and storage and transportation  
20 of the cartridge.
5. A method of manufacture of a fluidic cartridge for use with a dialysis machine,  
the method comprising  
providing a cartridge,  
25 securing a data storage unit on to the cartridge  
writing, to the data storage unit, information relating to one or more physical  
properties of the cartridge which are a result of tolerances applied during manufacture  
of the cartridge.
- 30 6. A fluidic cartridge for use with a dialysis machine, the fluidic cartridge being  
manufactured according to the method of claim 5.
7. A dialysis machine comprising

- an interface for receiving a fluidic cartridge according to any one of claims 1-4 and 6,
- data reading means for reading data stored on a data storage unit on a fluidic cartridge, and
- 5 a processor for receiving data stored on the data storage unit of the fluidic cartridge, wherein the processor comprises executable instructions, wherein the executable instructions comprise instructions for adjusting an operational parameter of the dialysis machine based on the received data.
- 10 8. The machine of claim 7, wherein an operational parameter comprises a conductivity cell calibration factor.
9. The machine of claim 8, wherein the executable instructions further comprise instructions for calculating the conductivity of dialysate solution in a conductivity cell
- 15 of the cartridge based on the conductivity cell calibration factor.
10. The machine of claim 7, wherein the dialysis machine further comprises transmitting means for transmitting data read by the data reading means to a remote storage facility.
- 20 11. A method of operating a dialysis machine, comprising the steps:
- providing a dialysis machine comprising means for reading data stored on a data storage facility of a dialysis cartridge,
- providing a dialysis cartridge for use with the dialysis machine, wherein the
- 25 cartridge comprises a data storage facility storing data relating to physical parameters of the cartridge which are a result of tolerances applied during manufacture of the cartridge,
- reading, by the dialysis machine, information stored on the cartridge,
- calculating, by the dialysis machine, a calibration factor based on the
- 30 information read from the data storage facility of the cartridge.

12. The method of claim 11, further comprising calculating, by the dialysis machine, the conductivity of dialysate in a conductivity cell of the cartridge based on the calculated calibration factor.
- 5 13. A cartridge for use in a portable dialysis machine, wherein the cartridge comprises
- data storage means for storing data, wherein the data storage means stores data relating to sterilisation of the cartridge, and wherein the data storage means is configured such that when the cartridge is connected to the dialysis machine, data stored
- 10 on the data storage means is read by the dialysis machine.
14. The cartridge of claim 13, wherein the stored data comprises information relating to whether the cartridge has been sterilised since it was last used.
- 15 15. The cartridge of claim 13 or claim 14, wherein the data storage means is at least one of an optical pattern, physical pattern, RFID chip or RFID tag.
16. The cartridge of claim 13, wherein the data storage means is configured to be written to by the dialysis machine.
- 20 17. The cartridge of claim 13, wherein the data on the data storage means data can be read and written to by a device other than a dialysis machine.
18. The cartridge of any one of claims 13 to 17, wherein data stored on the data
- 25 storage means further includes information relating to any one or more of the age of the cartridge, the intended function of the cartridge, the intended operation of the cartridge, the person or persons for whom the cartridge is to be used, the extent of usage of the cartridge, the intended geographical usage of the cartridge, the software intended for or required for use with the cartridge, the origin of the cartridge, sterilisation of the
- 30 cartridge and storage and transportation of the cartridge.

19. A portable dialysis machine, the machine comprising  
data reading means for reading data stored on data storage means of a cartridge  
when the cartridge is loaded in the machine,
- 5 a processor, wherein the processor is configured to receive the data from the  
data reading means and to determine, from the stored data, whether the cartridge is  
suitable for use with the machine,  
wherein the processor is further configured to output information to be displayed  
on a user interface of the machine, wherein the output information relates to the  
10 determination as to whether the cartridge is suitable for use by the machine.
20. The machine of claim 18, further comprising data writing means for writing data  
to a data storage means of a cartridge when the cartridge is loaded in the machine.
- 15 21. The machine of claim 19, wherein the data writing means is configured to write  
data relating to the usage of the cartridge after the cartridge has been used.
22. The dialysis machine of any of claims 18 to 20, wherein the dialysis machine  
further comprises transmitting means for transmitting data read by the data reading  
20 means to a remote storage facility.
23. A fluidic cartridge for use in a dialysis machine, wherein the cartridge comprises  
a data storage unit for storing data, wherein the data storage unit stores data relating to  
a patient treatment protocol.
- 25 24. A dialysis machine comprising a data reading means for reading data stored on  
the data storage unit of the fluidic cartridge of the seventh aspect when the cartridge is  
loaded in the machine, and a processor, wherein the processor is configured to receive  
the patient treatment protocol data read from the data storage unit by the data reading  
30 means and to operate the machine to deliver the patient treatment protocol.

Figure 1

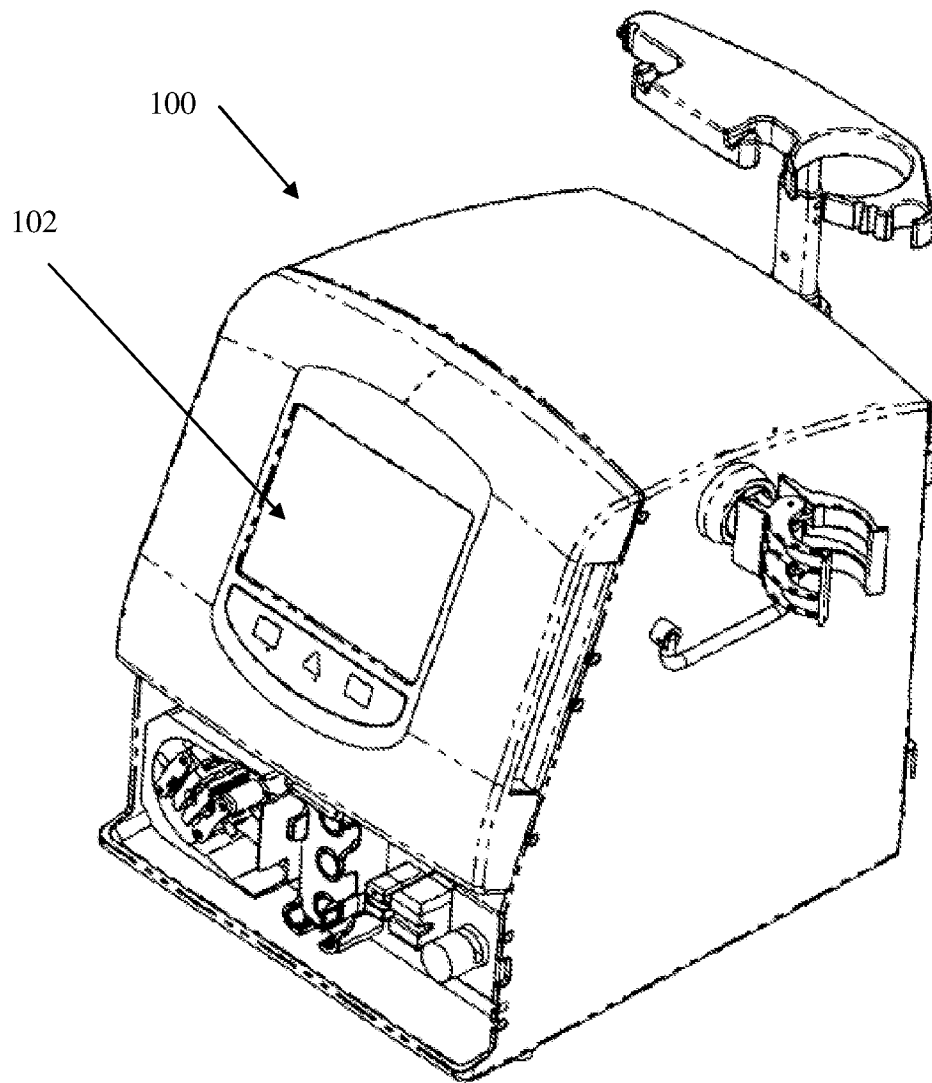


Figure 2

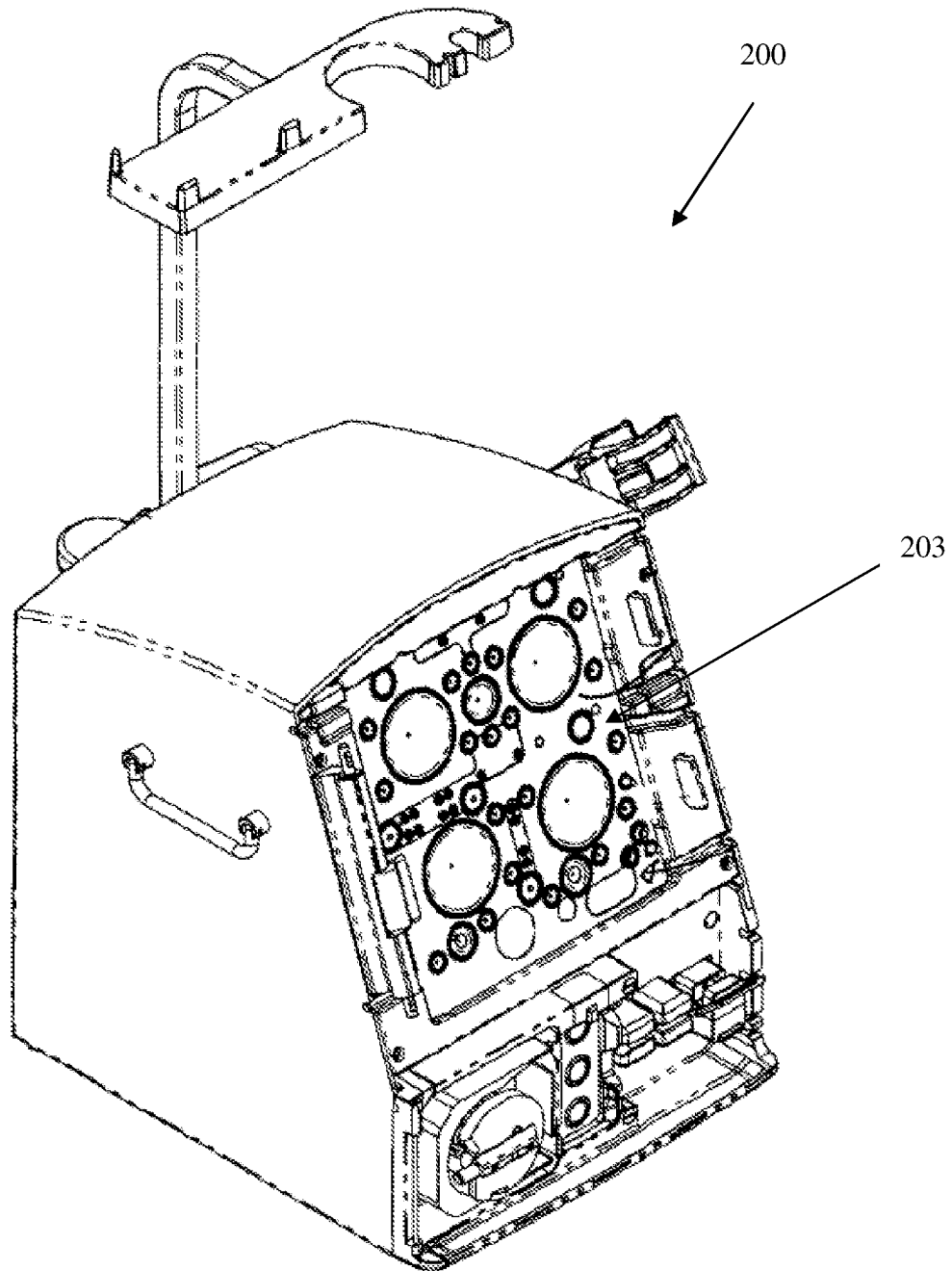
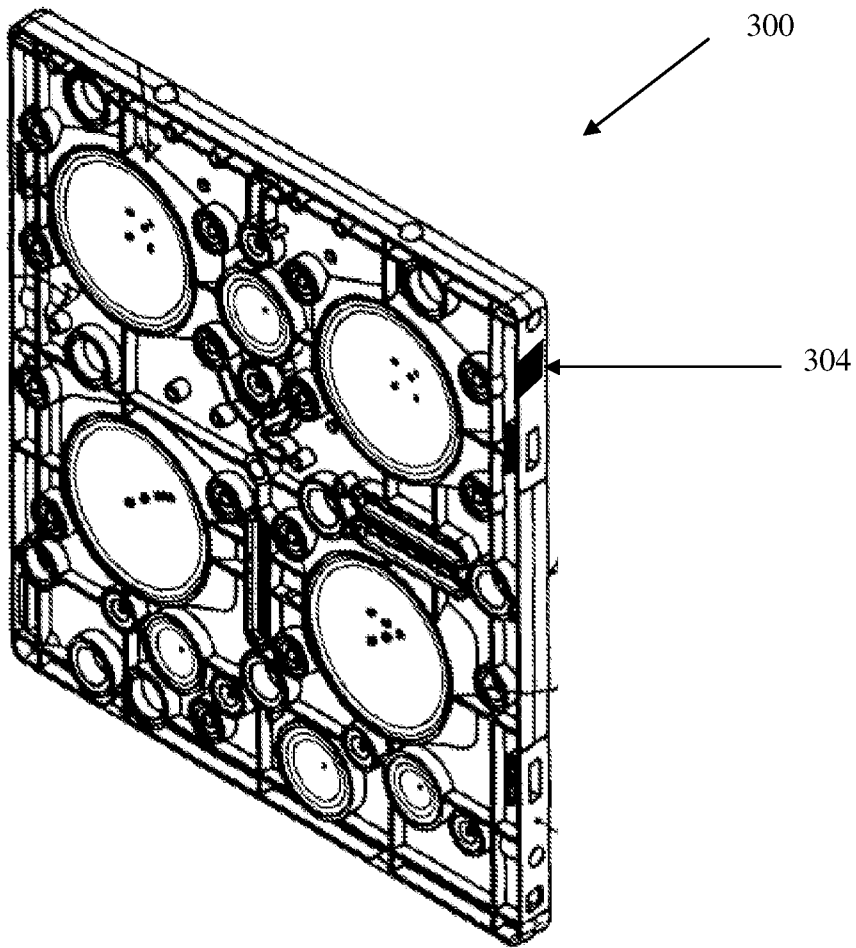
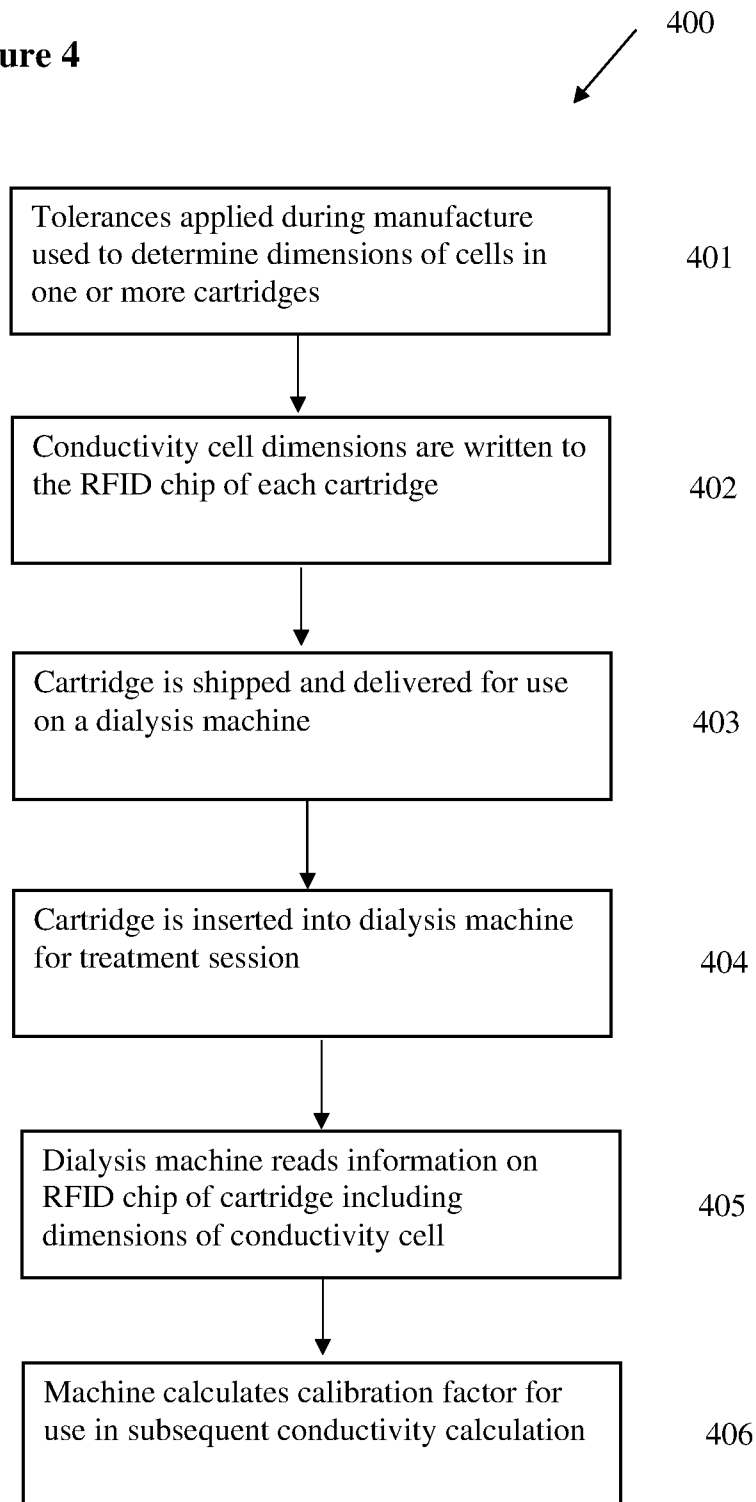


Figure 3



**Figure 4**

# INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2018/050797

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M1/14 A61M1/34  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 2015/359954 A1 (GERBER MARTIN T [US] ET AL) 17 December 2015 (2015-12-17)  paragraph [0141] - paragraph [0142];  figure 2a  paragraph [0148]  paragraph [0154] - paragraph [0156]  paragraph [0163]  paragraph [0167]  paragraph [0171]  paragraph [0189]  paragraph [0199] - paragraph [0202]  -----  -/--</p>	<p>1-7, 10, 13-24</p>

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

30 May 2018

Date of mailing of the international search report

12/06/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
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# INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2018/050797

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/238673 A1 (GERBER MARTIN T [US] ET AL) 27 August 2015 (2015-08-27) paragraph [0171] - paragraph [0173] paragraph [0184] - paragraph [0186] paragraph [0199] paragraph [0207] paragraph [0209] - paragraph [0210] -----	1-7,10, 13-24
X	US 2009/009290 A1 (KNEIP DANIEL [US] ET AL) 8 January 2009 (2009-01-08)  paragraph [0015]; figure 1B paragraph [0039] - paragraph [0041] paragraph [0053] - paragraph [0054] -----	1-4,6,7, 10,19, 21-24

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB2018/050797

### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **11, 12**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Claims 11 and 12 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv)/Rule 67.1(iv)PCT.**
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2018/050797

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2015359954	A1	17-12-2015	NONE
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US 2015238673	A1	27-08-2015	CN 104857584 A 26-08-2015
			CN 107596469 A 19-01-2018
			EP 3111377 A1 04-01-2017
			US 2015238673 A1 27-08-2015
			WO 2015130466 A1 03-09-2015
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			US 2009009290 A1 08-01-2009
			WO 2009006491 A2 08-01-2009
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